



# Vaccination Documentation: International Data Standards as an Essential Foundation

18 February 2021

10:30-12:00 EST/16:30-18:00 CET

# Agenda



- Introduction
- Urgency and Goals of the Proposed Project
- International Consensus Towards Vaccination Documentation
  - Current Landscape and Scope of Project
  - CDISC Initial DRAFT of Core Elements for Vaccine Administration Record Information
- Questions
- Breakout Groups for Discussion
- Comments from Breakout Groups
- Actions and Next Steps

# Issues Encountered in Managing Covid-19 Data

## New York Times (13 July 2020)

- “Before public health officials can manage the pandemic, they must deal with a broken data system that sends incomplete results in formats they can’t easily use.....**Health departments track the virus’s spread with a distinctly American patchwork:** a reporting system in which some test results arrive via smooth data feeds but others come by phone, email, physical mail or fax... These reports often come in duplicate, go to the wrong health department, or are missing crucial information...”

## Resolve to Save Lives - Report (21 July 2020)

- “The report found **critical gaps in the availability of information necessary to track and control COVID-19:** across the 50 states, only 40% of essential data points are being monitored and reported publicly. More than half the essential information—strategic intelligence that leaders need to turn the tide against COVID-19—is not reported at all.”

(See also <http://preventepidemics.org> )



## Protocol (7 July 2020)

- “The COVID-19 crisis laid bare all the ways that EHRs have fallen short—and what needs to be done....as with any systemic problem, there are endless root causes. One of them it the **lack of uniform standards for how data is entered into EHRs to begin with.**”

## Situation in Spain, Italy and the United States During the Pandemic

- The U.S. has over 56 different public health systems that all function differently; responsibility was distributed.
- Spain has 17 different regions; a national approach was in place for 3 months; there is now regional responsibility.
- Italy has different regions, however, during the pandemic, a national approach was instituted.

# Proposed Project

**Goal:** widely adopted and internationally implemented data standards documenting vaccine administration

**Use Cases:** travel, education, business safety, learning → knowledge

**Scope:** minimum set of core elements and metadata (including terminology/codelists) of key data related to vaccine administration

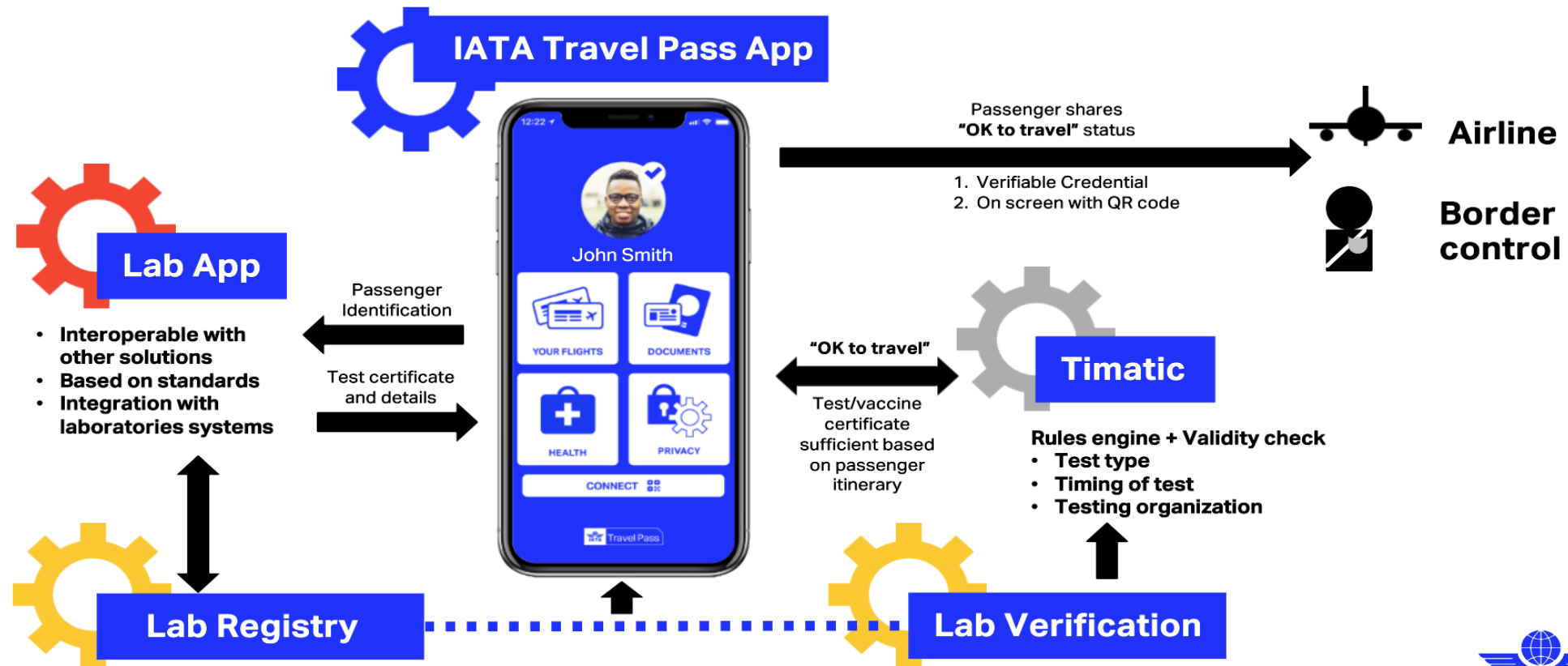
## Not for Discussion Today:

- Safety Information (pharmacovigilance, adverse event tracking)
- Credentialing information (security, confidentiality, privacy)
- Application development and technology solutions

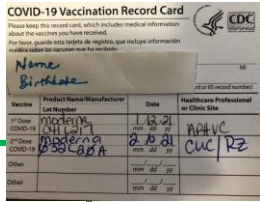
# International Air Transport Association (IATA)

IATA Website: “The fragmented and diverse set of COVID-19 testing requirements for entry and exit as well as the range of different types of tests (PCR, LAMP, antigen and spectroscopic) required by governments have created a challenging and complex environment for immigration authorities, passengers and airlines to navigate.”

## Overview



# The Case an International Data Standard



## Public Health




-> Databases within Various Regions, States and/or Countries




## Hospitals/Clinics

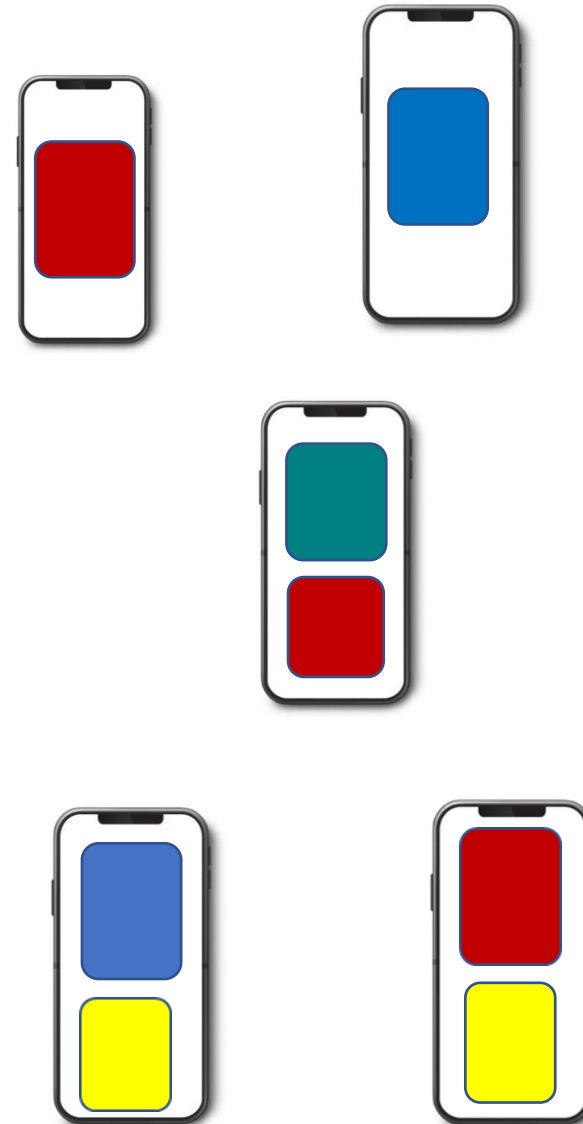
Electronic Health Records

**Public Health/Private Vaccine Documentation**  
Various Paper Records  
(Pharmacies, Gyms, Clinics, etc.)

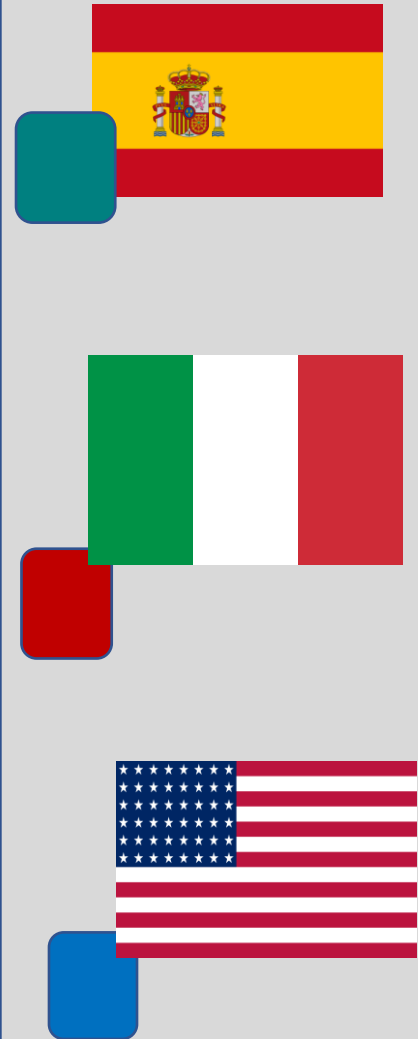
   = Vaccine Administration Data Content

 = Other data, e.g. testing, Tx

## Various Apps in Development



## Border Requirements for Vaccine Administration Data



To encourage adoption of a common international standard for vaccine administration data to support apps and the desired use cases, the standard must be simple and understandable, supporting data inputs from healthcare, research, public health, including:

- **Paper Forms (data entered later)**
  - eCase Report Forms
- **Public Health Databases, Registries**
  - **Electronic Health Records**

For vaccine documentation apps to be successful, the underlying data upon which they are based must be:

- **Accurate and meaningful**
  - **Accessible**
  - **Consistently defined**
- **Represented in a standard data format**

# Relevant Standards Initiatives

## Vaccine Credentialing Initiative (VCI)

VCI Coalition = CARIN Alliance, Cerner, Change Healthcare, The Commons Project Foundation, Epic, Evernorth, Mayo Clinic, Microsoft, MITRE, Oracle, Safe Health, Salesforce

HL7 Version 2.5.1  
Implementation Guide  
for Immunization Messaging  
(406 pages)

*SMART Health Cards  
specification, based on  
W3C Verifiable Credential  
and HL7 FHIR standards*

*Proposed  
International  
Minimum Set of  
Core Data  
Elements*



**European eHealth Network**  
Guidelines on proof of vaccination  
for medical purposes-  
basic interoperability elements

## Clinical Data Interchange Standards Consortium (CDISC)

Developed **international** therapeutic area standards for clinical research data to support regulatory decisions, including one for Covid-19 vaccines and therapies  
Released May 2020



# Harmonized Vaccine Administration Standard

- Harmonized set of core elements
  - European eHealth Network
  - CDISC
  - OMOP
  - HL7 CCD, US CORE (FHIR)
- Discussion today in breakout groups
- **Rapidly publish/disseminate core data elements for broad international comment**
- With sufficient interest, develop further and finalize standard through a robust, accredited, standards development process
- Produce a readily understandable Implementation Guide
- Ensure there is a Communication Plan



Photo by [National Cancer Institute](#) on [Unsplash](#)

# Proposed Core Data Elements

- **Vaccination Information**

- Disease or agent targeted
- Vaccine/Prophylaxis Medicinal Product & Trade Name
- Marketing Authorization Holder
- Manufacturer
- Expected number of doses (property)
- Vaccine Administered
- Batch/lot number
- Dose, Dose Unit
- Route of Administration
- Date of 1<sup>st</sup> dose
- Date of 2<sup>nd</sup> dose
- Booster, if applicable
- Administering center
- Administered by
- Country of vaccination
- Next vaccination date (optional)

- **Patient Identification Information**

- Name: First and last. Mother's maiden name
- Date of Birth, Month of Birth, Year of Birth
- Gender
- Address, City, County, State, Country, Post code
- Informed consent date - Day, month, year

- **Certificate Metadata**

- Certificate issuer
- Certificate Identifier
- Certificate Valid from (optional)
- Certificate Valid until (optional)
- Certificate Schema Version - Version of minimum dataset definition (E.g. 1.0)

Note - some fields will repeat (ex. dates, dose and dose unit)

# Controlled Terminology

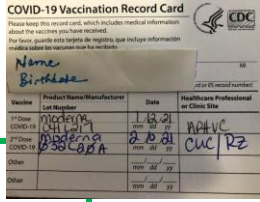
## EXAMPLE: Constrained List for 'Route of Vaccine Administration'

- Route of Administration
  - Intermuscular
  - Nasal
  - Oral
  - Percutaneous
  - Sublingual
  - Topical

<https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology>

AURICULAR (OTIC)	INTRAHEPATIC	IRRIGATION
BUCCAL	INTRAILEAL	LARYNGEAL
CONJUNCTIVAL	INTRAJEJUNAL	MICRODIALYSIS
CUTANEOUS	INTRALESIONAL	NASAL
DENTAL	INTRALUMINAL	NASOGASTRIC
DIETARY	INTRALYMPHATIC	NOT APPLICABLE
ELECTRO-OSMOSIS	INTRAMANDIBULAR	OCCLUSIVE DRESSING TECHNIQUE
ENDOCERVICAL	INTRAMEDULLARY	OPHTHALMIC
ENDOSINUSIAL	INTRAMENINGEAL	ORAL
ENDOTRACHEAL	INTRAMUSCULAR	ORAL GAVAGE
ENTERAL	INTRANODAL	OROMUCOSAL
EPIDURAL	INTRAOCULAR	OROPHARYNGEAL
EXTRA-AMNIOTIC	INTRAOSSEOUS	PARENTERAL
EXTRACORPOREAL	INTRAOVARIAN	PERCUTANEOUS
HEMODIALYSIS	INTRAPALATAL	PERIARTICULAR
INFILTRATION	INTRAPARENCHYMAL	PERIDURAL
INTERSTITIAL	INTRAPERICARDIAL	PERINEURAL
INTRA-ABDOMINAL	INTRAPERITONEAL	PERIODONTAL
INTRA-AMNIOTIC	INTRAPLEURAL	PERIVENOUS
INTRA-ARTERIAL	INTRAPROSTATIC	PHARYNGEAL
INTRA-ARTICULAR	INTRAPULMONARY	RECTAL
INTRABILIARY	INTRASINAL	RESPIRATORY (INHALATION)
INTRABRONCHIAL	INTRASPINAL	RETROBULBAR
INTRABURSAL	INTRASTOMAL	SOFT TISSUE
INTRACAMERAL	INTRASURGICAL SITE	SUBARACHNOID
INTRACARDIAC	INTRASYNOVIAL	SUBCONJUNCTIVAL
INTRACARTILAGINOUS	INTRATENDINOUS	SUBCUTANEOUS
INTRACAUDAL	INTRATESTICULAR	SUBLINGUAL
INTRACAVERNOUS	INTRATHALAMIC	SUBMUCOSAL
INTRACAVITARY	INTRATHECAL	SUBRETINAL
INTRACEREBRAL	INTRATHORACIC	SUBTENON
INTRACISTERNAL	INTRATUBULAR	SUPRACHOROIDAL
INTRACORNEAL	INTRATUMOR	TOPICAL
INTRACORONAL, DENTAL	INTRATYMPANIC	TRANSDERMAL
INTRACORONARY	INTRAUTERINE	TRANSMAMMARY
INTRACORPORUS CAVERNOSUM	INTRAVAGINAL	TRANSMUCOSAL
INTRADERMAL	INTRAVASCULAR	TRANSPLACENTAL
INTRADISCAL	INTRAVENOUS	TRANSTRACHEAL
INTRADUCTAL	INTRAVENOUS BOLUS	TRANSTYMPANIC
INTRADUODENAL	INTRAVENOUS DRIP	UNASSIGNED
INTRADURAL	INTRAVENTRICULAR	UNKNOWN
INTRAEPIDERMAL	INTRAVESICAL	URETERAL
INTRAESOPHAGEAL	INTRAVITREAL	URETHRAL
INTRAGASTRIC	IONTOPHORESIS	VAGINAL
INTRAGINGIVAL		

# The Case for an International Data Standard



## Public Health

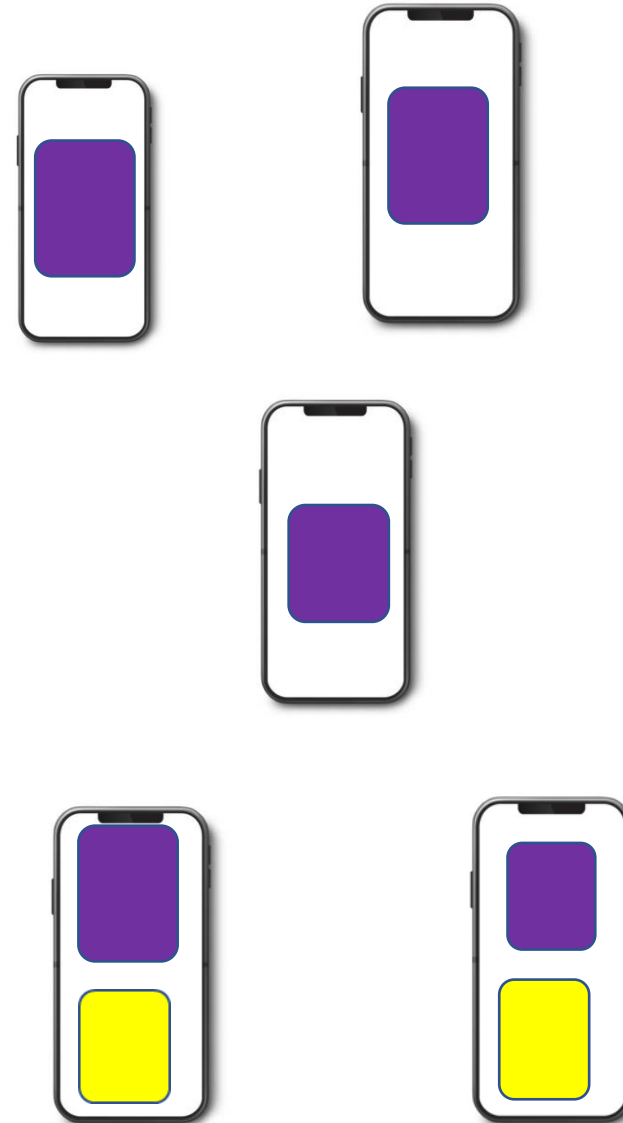
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## Hospitals/Clinics

Electronic Health Records

## Various Apps in Development



## Border Requirements for Vaccine Administration Data



## Public Health/Private Vaccine Documentation

Various Paper Records

(Pharmacies, Gyms, Clinics, etc.)

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# Potential Benefits of this Project

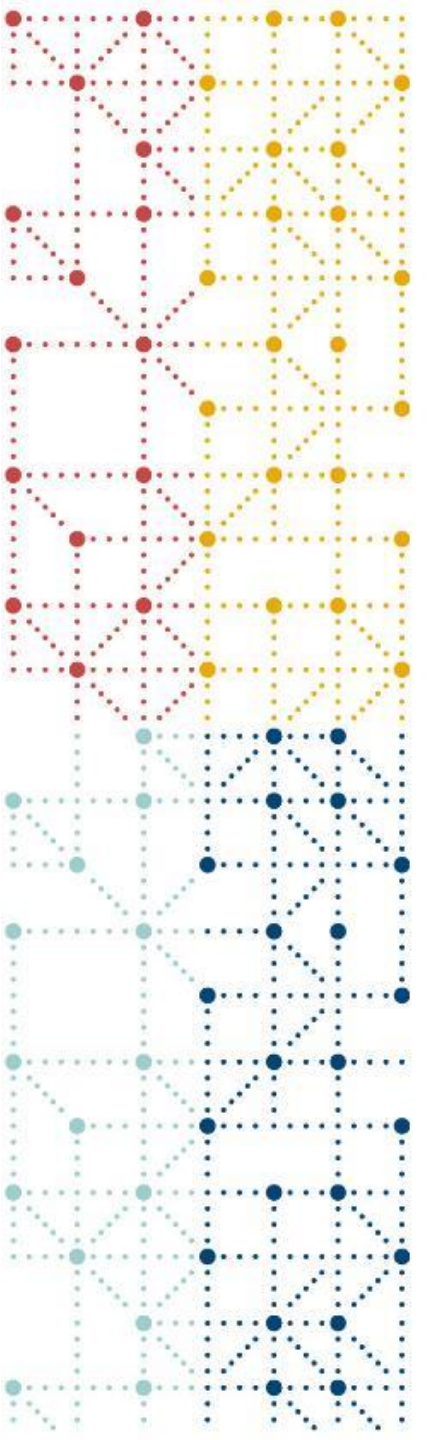
- International, interoperable, fit-for-use mappable record of vaccinations
- Easy to understand and implement for paper forms, electronic forms, EHRs
- Can be shared among a variety of providers (public health, hospitals, pharmacies, governmental agencies)
- Enable app developers to be successful in accessing the data they need so that they can innovate around user interfaces vs. contending with disparate data sources
- Allow travelers to have internationally acceptable proof of vaccination
- Allow educational institutions to track vaccinations to ensure safety of instructors and students
- Allow businesses to open more safely
- Enable learning from a wider variety of data sources with access to a more trustworthy and understandable data
- Enable secondary use in the future
  - De-identified patient level data
  - Standard testing data
- Supports regulatory missions related to pharmacovigilance, public health and welfare

# Breakout Group Discussion Questions



- Is the proposed minimum core set of data elements **missing anything essential**?
- Is there anything in the proposed minimum core set of data elements that is **unnecessary**?
- Does the group have **other recommendations** with respect to the core set of data elements proposed?
- What **other stakeholders** should be engaged and how?





# Breakout Group Reports

# Actions and Next Steps

*Facilitated by Dr. Charles Friedman*

- For Slides, Participant Bios, References, Notes from Today
  - [www.learninghealth.org](http://www.learninghealth.org) (Initiatives Tab)
- For the organizers' publication
  - [Learning Health Systems Journal Vol.5, Issue 1, January 2021](#))

[Addressing the Covid-19 pandemic and future public health challenges through global collaboration and a data-driven systems approach \(wiley.com\)](#)

- Questions...e-mail: [rkush@catalysisresearch.com](mailto:rkush@catalysisresearch.com)
- For further information on CDISC and the Covid-19 Therapeutic Area Standard
  - [www.cdisc.org](http://www.cdisc.org)
  - [www.cdisc.org/standards/therapeutic-areas/covid-19](http://www.cdisc.org/standards/therapeutic-areas/covid-19)

## Thank You All for Participating!